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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,439	12/05/2003	Scott A. Burton	59405US002	9418

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EXAMINER	
RONESI, VICKEY M	

ART UNIT	PAPER NUMBER
1714	

NOTIFICATION DATE	DELIVERY MODE
08/13/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com
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Office Action Summary	Application No.	Applicant(s)	
	10/728,439	BURTON ET AL.	
	Examiner	Art Unit	
	Vickey Ronesi	1714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12-50,53-55 and 58-93* is/are pending in the application.

4a) Of the above claim(s) *46,47,61-74 and 76-93* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12-45,48-50,53-55,58-60 and 75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-10,12-50,53-55 and 58-93* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :7/19/06, 5/21/07, 6/5/07, 8/2/07.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/21/2007 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

Election/Restrictions

3. In view of applicant's amendments filed on 5/21/2007, new a restriction requirement is set forth below.

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 12-45, 48-50, 53-55, 58-60, and 75, drawn to a composition, classified in class 523, subclass 122.

II. Claims 62-66, 70-74, 76-88, drawn to a method of making the composition, classified in class 427, subclass 212.

III. Claims 46, 47, 61, 67-69, and 89-93, drawn to an article, classified in class 427, subclass 2.31 and class 428, subclass 221.

The inventions are distinct, each from the other because:

5. Inventions II and I are related as process of making and product made.. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the silver oxide can be prepared outside the hydrophilic organic microparticles.

6. Inventions I and III are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product, and the species are patentably distinct (MPEP § 806.05(j)). In the instant case, the intermediate product is deemed to be useful as on non-medical articles such as clothing or formed into a non-medical sanitary article and the inventions are deemed patentably distinct because there is nothing on this record to show them to be obvious variants. Note that the method of using the composition on a wound claims (claims 61, 90, and 92) have been grouped with the medical article claims since the medical article and are patentably distinct as presently claimed.

7. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions cannot be used together because the method of making the composition is not capable of being used with the article containing the composition.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

9. During a telephone conversation with Ann Mueting on 8/2/2007 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-10, 12-45, 48-50, 53-55, 58-60, and 75. Affirmation of this election must be made by applicant in replying to this Office action. Claims 46, 47, 61-74, and 76-93 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

12. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Rejections - 35 USC § 112

13. Claims 53-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 53-55, the term "the hydrophobic phase" lacks antecedent basis.

Claim Rejections - 35 USC § 103

14. Claims 1-4, 6-9, 12, 19-39, 42-45, 48-50, 52, 53, 55, 58-60, and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asmus (US 5,270,358) alone or in view of Laurin et al (US 4,603,152).

Asmus discloses a composite (col. 40, lines 16-45) used in wound care (col. 44, lines 17-30) comprising 1-95 wt % a gel having a size of 1-600 microns (col. 19, lines 16-20) containing hydrcolloid (i.e., hydrophilic polymer) (col. 6, line 54 to col. 8, line 50) and a swelling agent; antimicrobial agents such as silver oxide (col. 12, lines 27-44); pressure sensitive adhesive (i.e.,

hydrophobic polymer in continuous phase) (col. 4, lines 53 to col. 6, line 29; specifically col. 5, line 6); water (col. 9, line 66-67) in exemplified amounts of 0-56 wt % (col. 24, Table 2, specifically Example 9); and other additives (col. 6, lines 3-4; col. 12, lines 50-68). Asmus teaches that the antimicrobial agents are included in the gel components and is therefore contained within the hydrophilic polymer (col. 12, lines 21-36).

With respect to claims 7-9, 11, 12, 19-23, 26-31, 34-39, 42-45, 52, 53, and 55-59, these claims are product-by-process claim and therefore "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Therefore, while the presently cited claims recite that a hydroxide source, is added to convert the metal compound into a metal oxide, given that Asmus discloses the use of silver oxide, the final composition of Asmus and that presently claimed is not different.

With respect to the particle size of absorbent (i.e., gel) particle in a nonhydrated form, given that the swelled gel has a particle size of 1 miron and that the weight ratio of hydrocolloid:swelling agent is (col. 40, lines 32-33), it is intrinsic that in an unswelled state the gel particles have a particle size less than 1 micron.

With respect to the utilization of secondary absorbent particles, it is the examiner's position that it is obvious to utilize more than one ingredient that does the same thing. It is well settled that it is prima facie obvious to combine two ingredients, each of which is targeted by the

prior art to be useful for the same purpose. *In re Lindner* 457 F,2d 506,509, 173 USPQ 356, 359 (CCPA 1972).

With respect to the water solubility of the bioactive compound, given that the microbial agents of Asmus are like those presently claimed, the microbial agents intrinsically have a solubility in water of at least 0.1 gram per liter in water.

Asmus fails to disclose the particle size of the antimicrobial agent such as silver oxide.

While Asmus does not disclose the particle size of the antimicrobial agent, it is the examiner's position that the size are result effective variables because changing them will clearly affect the type of product obtained. See MPEP § 2144.05 (B). Case law holds that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Evidence to support the examiner's position is found in Laurin et al which teaches that the size of antimicrobial agent (col. 3, lines 1-8) is critical in controlling the delivery time and tissue irritation considerations, wherein submicron sizes are preferred (col. 4, lines 50-68).

In view of this, it would have been obvious to one of ordinary skill in the art to utilize appropriate sizes of the antibacterial agent, including those within the scope of the present claims, so as to produce desired end results and thereby arrive at the presently cited claims.

15. Claims 5, 10, 40, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asmus (US 5,270,358) alone or in view of Laurin et al (US 4,603,152) and further in view of Ahmed et al (US 6,458,877).

The discussion with respect to Asmus and Laurin et al in paragraph 14 above is incorporated here by reference.

Asmus does not disclose the use of a hydrocolloid that it is a quarternary ammonium salt of an organic polymer.

Ahmed et al, like Asmus, discloses superabsorbent polymers (i.e., hydrocolloids) and teaches that quarternary ammonium salts of an organic polymer is a common hydrocolloid (col. 11, line 67).

Given that Asmus is open to the use of any suitable hydrocolloid material, it would have been obvious to utilize an ammonium salt as taught by Ahmed et al and thereby arrive at the presently cited claims.

16. Claims 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asmus (US 5,270,358) alone or in view of Laurin et al (US 4,603,152) and further in view of Yan et al (US 2003/0185889).

The discussion with respect to Asmus and Laurin et al in paragraph 14 above is incorporated here by reference.

Neither Asmus nor Laurin et al discloses the use of an ammonia source in its composition.

Yan et al teaches that in order to increase the solubility of silver oxide in water, the use of ammonia water is needed (paragraph 0029).

Given that the silver oxide in Asmus is utilized in a water, it would have been obvious to one of ordinary skill in the art to utilize ammonia or any of its derivative salts to increase the solubility of silver oxide as taught by Yan et al.

Double Patenting

17. Applicant's statement on page 18 of the amendment filed on 5/21/2007 regarding the right to argue the patentable distinctness of the below obviousness-type double patenting rejection upon identification of allowable subject matter. If the following double-patenting rejection is the only rejection remaining in this application and if there is a provisional obviousness-type double patenting rejection in the later-filed copending application, per USPTO practice, the examiner will withdraw the rejection.

18. Note that a statement of common ownership at the time of invention is required to preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g). It is suggested that applicant submit a statement such as, "Application X and Application Y were, at the time the invention of Application X was made, owned by Company Z." See MPEP § 706.02(l)(2).

19. Claims 1-10, 12, 19-45, 48-50, 53-55, 58-60, and 75 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15, 19-21, 27-39, 41-46, 49, 51, 53-63, and 70 of copending Application No. 10/728,577 (published as US 2004/0180093) alone or in view of Laurin et al (US 4,603,152).

US appl. '577 claims a polymer composition and a method of making the composition and medical articles thereof, wherein the composition comprises a bioactive agent, absorbent hydrophilic microparticles, and an organic polymer matrix. Even though US appl. '577 fails to claim a hydrophobic polymer as the matrix polymer, note page 2, lines 16-17, where US appl. '577 discloses the use of a hydrophobic matrix material that is continuous. Case law holds that those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in an application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 164 USPQ 619,622 (CCPA 1970).

The claims of US appl. '577 are silent with respect to the particle size of the bioactive agent or metal oxides as the bioactive agent.

While US appl. '577 does not disclose the particle size of the bioactive agent, it is the examiner's position that the size are result effective variables because changing them will clearly affect the type of product obtained. See MPEP § 2144.05 (B). Case law holds that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Evidence to support the examiner's position is found in Laurin et al which teaches that the size of a bioactive agent (col. 3, lines 1-8) is critical in controlling the delivery time and tissue irritation considerations, wherein submicron sizes are preferred (col. 4, lines 50-68).

In view of this, it would have been obvious to one of ordinary skill in the art to utilize appropriate sizes of the bioactive agent, including those within the scope of the present claims, so as to produce desired end results and thereby arrive at the presently cited claims.

This is a provisional obviousness-type double patenting rejection.

20. Claims 1-10, 12, 19-45, 48-50, 53-55, 58-60, and 75 are directed to an invention not patentably distinct from claims 1-15, 19-21, 27-39, 41-46, 49, 51, 53-63, and 70 of commonly assigned copending Application No. 10/728,577 (published as US 2004/0180093). Specifically, see the discussion set forth in paragraph 19 above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned copending Application No. 10/728,577 (published as US 2004/0180093), discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Response to Arguments

21. Applicant's arguments filed 5/21/2007 have been fully considered but they are not persuasive. Specifically, applicant argues that by adding claim language from now-canceled claim 51 renders the claims allowable over the prior art because the examiner did not reject claim 51 in the last office action.

In response, in the rejections above, the amended independent claims have been rejected because Asmus teaches the use of a hydrophobic matrix polymer.

Conclusion

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickey Ronesi whose telephone number is (571) 272-2701. The examiner can normally be reached on Monday - Friday, 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272-1119. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

8/2/2007
Vickey Ronesi

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